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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary

Application No.

10/659,970

Applicant(s)

LANGE ET AL.

Examiner

Renee Claytor

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-25 and 27-51 is/are pending in the application.
- 4a) Of the above claim(s) 31-48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-25, 27-30, 49, 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Claims 1-12, 14-25, 27-30, 49 and 51 are being examined on their merits herein. Claims 13 and 26 have been cancelled by Applicant and claims 31-48 and 50 have been withdrawn as directed to a non-elected invention.

In addressing the 35 USC 112, second paragraph rejection, Applicants have amended the claims to remove "(by weight)" and replaced with "by weight". This amendment to the claims is sufficient to overcome the rejection and the rejection is hereby withdrawn.

Applicant's arguments over the 35 USC 103(a) rejection over Fox (US Pg-Pub 2004/0071755) have been considered and are not found persuasive. Applicants have amended claim 51 to recite that the water-soluble film forming polymeric material comprises 40% by weight to about 70% by weight. As was pointed out in the previous Office Action, ~~Fox teaches that~~ Fox teaches that the base composition having the recited percentages is dried by subjecting to heat to form the final sheet product (see paragraph 0049, in particular), and thus the final sheet product can be expected to have a higher percent by weight of each ^{of} the components, such as the water-soluble film forming product due to the loss of water in the drying process. Therefore it would be obvious to vary and/or optimize the amount of the water soluble polymer in an effort to produce a composition with desired properties.

Applicant's arguments over the 35 USC 103(a) rejection over Fox (US Pg-Pub 2004/0071755) in view of Akihiro et al. (JP 11-209222) and further in view of Watanabe (JP 61-176512) have been considered and are not found persuasive. In accord with this rejection, Applicants argue that the Fox reference fails to disclose that the final product is configured for the lips and that it is capable of substantially dissolving on lips in no more than about 50 seconds. This argument is not persuasive because Fox teaches water-soluble sheets for use in the personal care field, which is considered analogous art in that the formulations are usable in various forms in personal care compositions (including face and body). The limitation of "capable of substantially dissolving on lips in no more than about 50 seconds" is a property of the water-soluble film forming polymer. Therefore, because the reference teaches the exact polymers as presently claimed, it would be obvious that the polymer will perform the same function because "capable of substantially dissolving on lips in no more than about 50 seconds" is an inherent property of the polymer.

Applicant further argues that the Akihiro et al. reference does not teach a water-soluble material in the moisturization pack and teaches that the pack is configured for a multi-layered structure. The Akihiro et al. reference was not used to address those particular limitations. The Akihiro et al. reference was used to simply teach that compositions that provide a humectant are useful in moisturization of the lips, further addressing the limitation of a lip treatment. The fact that the compositions of Akihiro et al. are multi-layered was not used to fill a deficiency, it merely complements the

teachings of Fox in that both compositions are sheet-like and further explains that a shared ingredient between both inventions is useful in lip products.

Applicant's arguments over Watanabe have been considered and are not persuasive. Applicant's argue that the film of the Watanabe reference is peeled from the surface of the lip and that it is not taught that the skin film is capable of dissolving on the lips in no more than about 50 seconds. This is not persuasive because Watanabe teaches the same ingredients that are used in the present invention, i.e., polyvinylpyrrolidone, glycerin and lanolin (Example 4). The limitation of "capable of substantially dissolving on lips in no more than about 50 seconds" is a property of the water-soluble film forming polymer. Therefore, because the reference teaches the exact polymers as presently claimed, it would be obvious that the polymer will perform the same function because "capable of substantially dissolving on lips in no more than about 50 seconds" is an inherent property of the polymer. It is further noted that in the abstract as well as the body of the reference, Watanabe teaches lip products comprised of a water-soluble film forming polymeric material, a moisturizing agent, and a solidifying agent and in the amounts given in the instant claim 1.

Applicant's arguments over the 35 USC 103(a) rejection over Fox (US Pg-Pub 2004/0071755) in view of Akihiro et al. (JP-11-209222) and Watanabe (JP-61-176512) and further in view of Yang et al. (WO 03/030881) have been considered and are not found to be persuasive. The arguments presented over Fox in view of Akihiro and Watanabe were addressed above. Applicant's argue that the Yang et al. reference does not teach that their delivery system can treat or moisturize the lips and is directed

Art Unit: 1617

to an edible, ingestible system for delivering active ingredients. Applicants also argue that Yang et al. teach away from the invention because the delivery system is a multi-layered film. This argument is not persuasive because as pointed out in the previous Office Action, Yang teaches that not only is the film ingestible, but that it is also capable of delivering pharmaceutical, cosmetic or biologically active agents. Further Yang teaches that pullulan is a water-soluble polymer suitable for forming water soluble and dissolvable films and/or sheets for the delivery of cosmetic and/or pharmaceutical agents. Further, Yang et al. was used to teach that pullulan is a water-soluble polymer that suitable for forming water soluble and dissolvable films and/or sheets for the delivery of cosmetic and/or pharmaceutical agents. This reference was not relied upon to teach any form of layering.

Due to Applicant's amendments to the claims, the following modified grounds of rejections are being given below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0071755 to Priscilla S. Fox, published April 15, 2004.

Fox teaches a composition in the form of a water soluble sheet for use in the personal care field (see abstract, in particular.) Fox teaches that the sheets comprise a base composition including a water soluble film forming polymer and a humectant (moisturizing agent), and can also comprise skin care ingredients (see abstract, in particular.) Fox teaches that the water soluble film releases the skin care ingredients upon exposure to sufficient moisture (see paragraph 0005, in particular.) Accordingly, it is considered that Fox teaches a single layer film having a water-soluble film-forming polymeric material and a moisturizing agent (humectant) as recited in the claim.

Regarding the solidifying agent, it is noted that Fox teaches that various soaps can be added to the composition, such as sodium octanoate and potassium soaps (see paragraph 0033, in particular.) Thus, Fox teaches providing metal soaps, which are disclosed as being suitable as "solidifying agents" in paragraph 0034 of the instant Specification.

Fox does not specifically exemplify a composition having the recited components in the specific weight percentages as claimed.

However, Fox teaches a general range that is suitable for the water-soluble polymer in the "base composition." It is furthermore noted that Fox teaches that the base composition having the recited percentages is dried by subjecting to heat to form the final sheet product (see paragraph 0049, in particular), and thus the final sheet product can be expected to have a higher percent by weight of each of the components, such as the water-soluble film forming product due to the loss of water in the drying process. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the water-soluble polymer provided in the composition, according to the guidance provided by Fox, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Fox et al. does teach that the composition contains from 0.75% to 12% by weight of the humectant (moisturizing agent) (see paragraph 0009, in particular), and between 2% to 22% by weight of the soap (solidifying agent) (see paragraph 0033, in particular), which are amounts that meet and/or overlap with the ranges as claimed.

Claims 1-12, 14-18 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0071755 to Priscilla S. Fox, published April 15, 2004, in view of JP 11-209222 to Akihiro et al, published August 3, 1999, and further in view of JP 61-176512 to Watanabe, published August 8, 1986.

Fox teaches a composition in the form of a water soluble sheet for use in the personal care field (see abstract, in particular). Fox teaches that the sheets comprise a base composition including a water soluble film forming polymer and a humectant (moisturizing agent), and can also comprise skin care ingredients (see abstract, in particular). Fox teaches that the water soluble film releases the skin care ingredients upon exposure to sufficient moisture (see paragraph 0005, in particular). Accordingly, it is considered that Fox teaches a single layer film having a water-soluble film-forming polymeric material and a moisturizing agent (humectant) as recited in the claim.

Regarding the amounts of each component provided, Fox et al. teaches that the composition can contain from 0.75-5% by weight of the water soluble polymer, from 0.75% to 12% by weight of the humectant (moisturizing agent), which are amounts that meet and/or overlap with the ranges as claimed. It is furthermore noted that Fox teaches that the base composition having the recited percentages is dried by subjecting to heat to form the final sheet product (see paragraph 0049, in particular), and thus the final sheet product can be expected to have a higher percent by weight of each or the

Art Unit: 1617

components, due to the loss of water in the drying process. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the ingredients provided in the composition, according to the guidance provided by Fox, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Fox does not specifically teach that the product is sized and configured for application to the lips, as recited in claim 1. Fox also does not specifically teach providing a "solidifying agent" such as one of those recited in claim 10 that is suitable for lip care treatment in particular. However, Fox does teach that skin conditioning ingredients such as emollients and humectants can be added to the water soluble sheet to provide these ingredients to skin.

Akihiro et al. teaches that a sheet-like humectant pack can be provided for the treatment of lips (see abstract, in particular), and especially to moisturize dry lips by providing a humectant (see abstract and paragraph 0001, in particular). Akihiro et al. teaches that sheets for application to the lips can be sized and configured to fit the lips (see paragraph 0020, in particular).

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the water soluble skin care sheet of Fox in a form that is sized and configured for application to lips, as in the sheet taught by Akihiro et al, because Fox teaches the sheet is capable of delivering skin care ingredients such as humectants and emollients to skin, whereas Akihiro et al. teaches that the lips are a part of the skin that it is known can be treated via application of sheet-type compositions, such as sheet compositions that deliver humectants to moisturize the lips, and that it is also known to size and configure such sheet compositions for lip application. Thus, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the skin care sheet of Fox in a size and configuration suitable for application to lips, with the expectation of providing a sheet composition capable of imparting cosmetic benefits, such as moisturizing benefits, to the lips.

Fox and Akihiro et al. do not specifically teach providing a "solidifying agent" in the lip care composition, such as one of those recited in claim 10. However, it is noted that Fox teaches that a wide variety of skin care ingredients including various emollients and humectants can also be added to the composition (see paragraphs 0015 and 0037-0038, in particular.) Fox and Akihiro also teach that the lips can be treated to moisturize the lips, as discussed above.

Watanabe teaches that drying and chapping of the lips can be treated by providing to the lips a humectant and an oleaginous wax that is effective to supply the skin with moderate oiliness, such as olive oil and lanolin (an animal wax) (see abstract, in particular), and thus teaches the solidifying agents as recited in claims 1 and 10.

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the oleaginous wax of Watanabe in the lip treatment composition of Fox and Akihiro et al, because Fox and Akihiro et al. teach that lips can be treated to moisturize with the treatment sheets, and that such sheets can contain treatment actives such as moisturizers and humectants, and Watanabe teaches that oleaginous waxes can be provided to treat dry and chapped lips. Thus, it is considered that one of ordinary skill in the art would have found it obvious to provide the oleaginous waxes as a skin care additive in the lip treatment sheets of Fox and Akihiro et al, with the expectation of providing a suitable skin care active capable of moisturizing and treating dry lips.

Regarding the amount of oleaginous wax provided, it is noted that Fox teaches that up to 50% by weight of the base composition can be added skin feel ingredients such as the humectants and moisturizers (see paragraphs 0037-0039, in particular), which is an amount that meets and/or overlaps with that claimed. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the oleaginous wax

Art Unit: 1617

provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Accordingly, claims 1 and 10 are considered to be obvious over the teachings of Fox, Akihiro et al. and Watanabe.

Regarding claims 2-3, it is noted, as discussed above, that Fox teaches a general range that is suitable for the water-soluble polymer in the "base composition." It is furthermore noted that Fox teaches that the base composition having the recited percentages is dried by subjecting to heat to form the final sheet product (see paragraph 0049, in particular), and thus the final sheet product can be expected to have a higher percent by weight of each of the components, such as the water-soluble film forming product due to the loss of water in the drying process. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the water-soluble polymer provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 4, Fox teaches that the water-soluble film forming polymeric material can be polyvinylpyrrolidone (see paragraph 0010, in particular), as recited in the claim.

Regarding claim 5, Fox teaches that the humectant can be present in an amount of from 0.75% to 12% (see paragraph 0009, in particular), which is an amount that meets and/or overlaps with that claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of humectant provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 6-7, Fox teaches that a preferred humectant is propylene glycol (see paragraph 0009, in particular), and can also include other humectants such as glycerin (see paragraph 0012, in particular), as recited in the claims.

Regarding claims 8-9, Fox teaches that other skin conditioning agents added to the composition can include petrolatum (see paragraph 0038, in particular), and thus teaches providing the occlusive-type moisturizing agent as claimed.

Regarding claims 11-12, it is noted that Fox teaches various methods of forming the sheet (see paragraphs 0014-0017, in particular) and also teaches that different amounts of the ingredients, such as the magnesium aluminum silicate, can result in more viscous base compositions that affect the thickness of the resulting sheet product (see paragraph 0009, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the ingredients such as the magnesium aluminum silicate provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a sheet composition having desired properties, such as a desired thickness. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the limitation of the capability of the composition to substantially dissolve in a certain amount of time in claims 1, 49 and 14-16, it is noted that Fox teaches that various ingredients in the compositions, such as the type and amount of surfactant provided, can affect the solubility and dissolution rate of the composition (see

Art Unit: 1617

paragraph 0033, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount and type of the ingredients provided in the sheet composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe to provide a composition having desired dissolving properties, such as a desired dissolving duration. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the length of the product as recited in claim 17, it is noted that Fox, Akihiro et al. and Watanabe render obvious shaping and configuring the composition for application to lips, as discussed above. Accordingly, it is considered that one of ordinary skill in the art would have found it obvious based on the teachings of these references to provide a length of the sheet that is suitable to fit on at least a portion of the lips, such as a length of no more than about 8 centimeters, with the expectation of providing a suitable treatment composition for the lips.

Regarding claim 18, Fox teaches that the composition can contain aloe, vitamin E acetate, and others (see paragraph 0038, in particular), as well as antibacterial agents (see paragraph 0046, in particular), and thus teaches providing pharmaceutically acceptable agents and antimicrobials, as recited in the claim.

Regarding claim 49, Fox and Akihiro et al. render obvious a single-use lip treatment that is sized and configured for application to the lips, and that contains the water-soluble film forming polymeric material, the moisturizing agent and solidifying agent in the amounts as claimed, as has been discussed for claim 1 above. Fox furthermore teaches that the composition can contain the vinyl polymer that is polyvinyl alcohol (see paragraph 0009, in particular), which is a water-dispersible polymer as indicated by Applicants on page 8 of the Specification. Fox teaches that the polyvinyl alcohol can be provided in an amount of from about 6.5% to about 23% by weight of the composition (see paragraph 0009, in particular), which is an amount that meets and/or overlaps with the amount recited in the claim. It is furthermore noted that Fox teaches that the base composition having the recited percentages is dried by subjecting to heat to form the final sheet product (see paragraph 0049, in particular), and thus the final sheet product can be expected to have a higher percent by weight of each or the components, due to the loss of water in the drying process. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the polyvinyl alcohol provided in the composition, according to the guidance provided by Fox, Akihiro et al. and Watanabe, to provide a composition having desired properties, such as desired skin benefit delivering properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 19-25 and 27-30 are rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0071755 to Priscilla S. Fox, published April 15, 2004, in view of JP 11-209222 to Akihiro et al, published August 3, 1999 and JP 61-176512 to Watanabe, published August 8, 1986, and further in view of WO 03/030881 A1 to Yang et al, published April 17, 2003.

Fox, Akihiro et al. and Watanabe are applied as discussed for claim 1 above, and render obvious a dissolving lip moisturizing product comprising a water-soluble polymer, a humectant that can comprise glycerin, and a solidifying agent that can be an oleaginous wax, in the amounts as claimed, and that is sized and configured for application to lips.

Fox, Akihiro et al. and Watanabe do not specifically teach that the dissolvable product contains pullulan, as required by claim 19. However, Fox teaches that the base composition for the film is made up of a water soluble polymer and polyvinyl alcohol (see paragraph 0009, in particular.)

Yang teaches water-soluble delivery systems in the form of a film and comprising a glucan (see abstract, in particular). Yang teaches that the film is ingestible, but that it is also capable of delivering pharmaceutical, cosmetic or biologically active agents (see abstract, in particular.) Yang teaches that the polymer pullulan is the preferred glucan, because of its high water solubility (see pages 1, 3 and 5), and thus teaches that

Art Unit: 1617

pullulan is a water-soluble polymer suitable for forming water soluble and dissolvable films and/or sheets for the delivery of cosmetic and/or pharmaceutical agents. Yang et al. also teaches that the pullulan can be suitably used in combination with other polymeric materials to form the film, such as polyvinyl alcohol (see page 5, lines 20-35, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the pullulan of Yang in the dissolving sheet composition of Fox, Akihiro and Watanabe, because Fox, Akihiro and Watanabe teach the dissolving sheet comprises a water soluble polymer, and Yang teaches that pullulan is a water soluble polymer that can be advantageously used in dissolving film preparations, and that is also suitably used in combination with polyvinyl alcohol, as taught by Fox, Akihiro et al. and Watanabe. Thus, one of ordinary skill in the art would have been motivated provide pullulan as the water soluble polymer in the sheet preparation of Fox, Akihiro et al. and Watanabe, with the expectation of providing a polymer that is suitable for forming the dissolving sheet compositions, and that can also be suitably combined with polyvinyl alcohol for forming such compositions. Accordingly, claim 19 is considered to be obvious over the teachings of Fox, Akihiro et al, Watanabe and Yang et al.

Regarding the amounts of pullulan and glycerin each component provided, as recited in claims 20-22, Fox et al. teaches that the composition can contain from 0.75-

Art Unit: 1617

5% by weight of the water soluble polymer, and from 0.75% to 12% by weight of the humectant (moisturizing agent), which are amounts that meet and/or overlap with the ranges as claimed. It is furthermore noted that Fox teaches that the base composition having the recited percentages is dried by subjecting to heat to form the final sheet product (see paragraph 0049, in particular), and thus the final sheet product can be expected to have a higher percent by weight of each of the components, due to the loss of water in the drying process. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the ingredients provided in the composition, according to the guidance provided by Fox, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 23, Watanabe teaches providing an oleaginous wax that is effective to supply the skin with moderate oiliness, such as olive oil and lanolin (an animal wax) (see abstract, in particular), as has been discussed for claim 1 above, and thus teaches the solidifying agents as recited in claim 23.

Regarding claims 24-25, it is noted that Fox teaches various methods of forming the sheet (see paragraphs 0014-0017, in particular) and also teaches that different

Art Unit: 1617

amounts of the ingredients, such as the magnesium aluminum silicate, can result in more viscous base compositions that affect the thickness of the resulting sheet product (see paragraph 0009, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the ingredients such as the magnesium aluminum silicate provided in the composition, according to the guidance provided by Fox, Akihiro et al, Watanabe and Yang, to provide a sheet composition having desired properties, such as a desired thickness. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the limitation of the capability of the composition to substantially dissolve in a certain amount of time in claims 19 and 27-28, it is noted that Fox teaches that various ingredients in the compositions, such as the type and amount of surfactant provided, can affect the solubility and dissolution rate of the composition (see paragraph 0033, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount and type of the ingredients provided in the sheet composition, according to the guidance provided by Fox, Akihiro et al, Watanabe and Yang, to provide a composition having desired dissolving properties, such as a desired dissolving duration. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it

Art Unit: 1617

is not inventive to discover the optimum or workable ranges by routine experimentation."

In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the length of the product as recited in claim 29, it is noted that Fox, Akihiro et al, Watanabe and Yang render obvious shaping and configuring the composition for application to lips, as discussed above. Accordingly, it is considered that one of ordinary skill in the art would have found it obvious based on the teachings of these references to provide a length of the sheet that is suitable to fit on at least a portion of the lips, such as a length of no more than about 8 centimeters, with the expectation of providing a suitable treatment composition for the lips.

Regarding claim 30, Fox teaches that the composition can contain aloe, vitamin E acetate, and others (see paragraph 0038, in particular), as well as antibacterial agents (see paragraph 0046, in particular), and thus teaches providing pharmaceutically acceptable agents and antimicrobials, as recited in the claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 1617

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

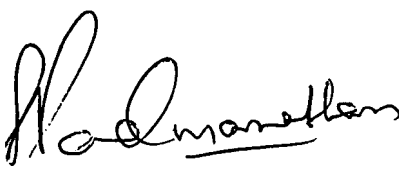
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER